Package leaflet: Information for the user

Phenytoin Sodium Milpharm 100 mg Capsules, Hard
Phenytoin Sodium Milpharm 300 mg Capsules, Hard

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Phenytoin Sodium is and what it is used for
2. What you need to know before you take Phenytoin Sodium
3. How to take Phenytoin Sodium
4. Possible side effects
5. How to store Phenytoin Sodium
6. Contents of the pack and other information

1. What Phenytoin Sodium is and what it is used for

Phenytoin Sodium Milpharm capsules are one of a group of medicines called anti-epileptic drugs; these medicines are used to treat epilepsy.

Phenytoin Sodium Milpharm capsules can be used to control a variety of epileptic conditions, to control or prevent seizures during or after brain surgery or severe head injury. Phenytoin Sodium can also be used to treat trigeminal neuralgia (facial nerve pain).

You should ask your doctor if you are unsure why you have been given Phenytoin Sodium.

2. What you need to know before you take Phenytoin Sodium

Do not take Phenytoin Sodium:
- if you are allergic to Phenytoin, or any of the other ingredients of this medicine (listed in section 6).
- if you are allergic to other medicines with a similar chemical structure to Phenytoin (e.g. hydantoins).

Warnings and precautions

Talk to your doctor, pharmacist or nurse before taking Phenytoin Sodium.

Medicines are not always suitable for everyone. Your doctor needs to know before you take Phenytoin Sodium if you suffer from or have suffered in the past from any of the following conditions:

- Liver disease.
- Kidney disease.
- Porphyria (an inherited disease that affects haemoglobin biosynthesis).

The following symptoms have been reported in some people treated with phenytoin at recommended doses:

- shortness of breath, becoming unconscious, or unresponsive. All can be the symptoms of the sudden, unexpected stopping of the heart (known as cardiac arrest). If you or someone you know is taking Phenytoin and experiencing these symptoms, **seek immediate medical support**.
- severe allergic reactions like swelling of the eyelids, face, lips, mouth and / or throat, as well as the tongue may cause difficulty in breathing or swallowing (known as angioedema) and sudden wheeziness.
- All these can be symptoms leading to a sudden, unexpected stopping of the heart (known as cardiac arrest). **Stop taking your medicine and seek immediate medical help**.
- slower heartbeat (known as bradycardia).

A small number of people being treated with antiepileptics such as phenytoin sodium have had thoughts of harming or killing themselves. If at any time you have these thoughts, immediately contact your doctor.

Potentially life-threatening skin rashes (Stevens-Johnson syndrome, toxic epidermal necrolysis) have been reported with the use of Phenytoin Sodium, appearing initially as reddish target-like spots or circular patches often with central blisters on the trunk. Additional signs to look for include ulcers in the mouth, throat, nose, genitals and conjunctivitis (red and swollen eyes). These potentially life-threatening skin rashes are often accompanied by flu-like symptoms, including fever at the initiation of treatment. The rash may progress to widespread blistering or peeling of the skin. The highest risk for occurrence of serious skin reactions is within the first weeks of treatment. If you have developed Stevens-Johnson syndrome or toxic epidermal necrolysis with the use of Phenytoin Sodium, you must not be re-started on Phenytoin Sodium at any time.

If you develop a rash or these skin symptoms, stop taking Phenytoin Sodium, seek urgent advice from a doctor and tell them that you are taking this medicine. Consult your doctor before permanently discontinuing Phenytoin Sodium. If you suddenly stop taking this medicine you may have a seizure.

Talk to you doctor before taking Phenytoin Sodium if you are of Taiwanese, Japanese, Malaysian or Thai origin and tests have shown that you carry the genetic variant CYP2C9*3.

Serious skin side effects can rarely occur during treatment with Phenytoin Sodium. This risk may be associated with a variant in genes in a subject with Chinese or Thai origin. If you are of such origin and have been tested previously carrying this genetic variant (HLA-B*1502), discuss this with your doctor before taking Phenytoin Sodium.

There is a risk of harm to the unborn child if Phenytoin Sodium capsules are used during pregnancy. Women of childbearing age should use effective contraception during treatment with Phenytoin Sodium (see Pregnancy, contraception in women, and breast-feeding).

Other medicines and Phenytoin Sodium

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Some medicines can affect the way Phenytoin Sodium work and Phenytoin Sodium themselves can reduce the effectiveness of other medicines taken at the same time. These include:

- Medicines used for heart and circulation problems (amiodarone, digoxin, furosemide, reserpine, ticagrelor,warfarin, calcium channel blockers e.g. diltiazem, mexiletine, nicardipine, nifedipine, nimodipine, disopyramide and verapamil)
- Medicines used to lower blood cholesterol, (e.g. atorvastatin, fluvastatin and simvastatin)
- Medicines used for epilepsy (carbamazepine, lacosamide, lamotrigine, oxcarbazepine, phenobarbital, sodium valproate, topiramate and valproic acid, succinimides e.g. ethosuximide and vigabatrin)

- Medicines used to treat fungal infections (e.g. amphotericin B, fluconazole, itraconazole, ketoconazole, miconazole, posaconazole and voriconazole)
- Medicines used for tuberculosis and other infections (chloramphenicol, clarithromycin, isoniazid, rifampicin, sulphonamides, sulfadiazine, sulfamethoxazole-trimethoprim, doxycycline, ciprofloxacin, efavirenz, fosamprenavir, indinavir, lopinavir/ritonavir, ritonavir and saquinavir)
- Medicines used for stomach ulcers (omeprazole, sucralfate, the medicines known as H_2 antagonists e.g. cimetidine and some antacids)
- Medicines used for asthma and bronchitis (theophylline)
- Medicines used for pain and inflammation (salicylates e.g. aspirin and steroids)
- Medicines used for sleeplessness, depression and psychiatric disorders (chlordiazepoxide, clozapine, diazepam, disulfiram, fluoxetine, methylphenidate, paroxetine, phenothiazines, trazodone, tricyclic antidepressants, fluvoxamine, quetiapine and sertraline)
- Medicines used for diabetes (tolbutamide).
- Some hormone replacement therapies (oestrogens), oral contraceptives (the birth control pill)
- Medicines used for organ and tissue transplants, to prevent rejection (ciclosporin and tacrolimus)
- Medicines used for cancer (antineoplastic agents, e.g.bleomycin, capecitabine, carboplatin, cisplatin, doxorubicin, fluorouracil and methotrexate)
- Muscle relaxants used for surgery (neuromuscular blockers), some anaesthetic drugs (methadone)
    - Medicines used as anticoagulants (e.g. rivaroxaban, dabigatran, apixaban, edoxaban)
- Some products available without a prescription (folic acid, theophylline, St John's Wort, vitamin D).

Your doctor may need to test the amount of Phenytoin in your blood to help decide if any of these medicines are affecting your treatment.

The herbal preparation St John's wort (*Hypericum perforatum*) should **not** be taken at the same time as this medicine. If you already take St John's Wort, consult your doctor before stopping the St John's Wort preparation.

Phenytoin Sodium may also interfere with certain laboratory tests that you may be given.

Phenytoin Sodium with food, drink and alcohol

Phenytoin Sodium can be taken before or after food and drinks. Drinking a lot of alcohol can also affect the concentration of Phenytoin in your blood.

Pregnancy, contraception in women, breast-feeding

Pregnancy

What you should know about the use of antiepileptic drugs in pregnancy

If you are pregnant, or think you may be pregnant, you must tell your doctor straight away and discuss possible risks the epilepsy medicine you are taking might pose to your unborn baby.

If you are planning to become pregnant you should discuss your epilepsy treatment with your doctor as early as possible before you become pregnant.

You should not stop your treatment without discussing this with your doctor. Suddenly stopping may lead to breakthrough seizures which may harm you and your unborn baby. It is important that your epilepsy is well controlled. Taking phenytoin during pregnancy increases the chance that the baby may have a physical birth abnormality.

Studies with women treated with phenytoin for epilepsy during pregnancy have shown that around 6 babies in every 100 will have serious physical birth abnormalities. This compares to 2-3 babies in every 100 born to women who don't have epilepsy.

The most common types of serious physical birth abnormalities (major congenital malformations) reported for phenytoin include abnormalities of the lip and palate, heart, skull, nail and finger disorders and growth abnormalities. Some of these may occur together as part of a fetal hydantoin syndrome.

Taking more than one epilepsy medicine at the same time may also increase the risk of physical birth abnormalities. Where possible, your doctor will consider using one epilepsy medicine only to control your epilepsy.

Your doctor may advise you to take folic acid if you're planning to become pregnant and while you're pregnant. Your doctor may adjust your epilepsy medicine when you take folic acid.

Some studies observed that taking phenytoin during pregnancy increases the chance that the baby may have problems affecting learning and thinking abilities.

If you take Phenytoin Sodium during pregnancy, your baby is also at risk for bleeding problems right after birth. Your doctor may give you and your baby a medicine to prevent this. Moreover, your child should be closely monitored.

Contraception in women

If you are a woman of childbearing age and are not planning a pregnancy, you should use effective contraception during treatment with Phenytoin Sodium. Phenytoin Sodium may affect how hormonal contraceptives, such as the contraceptive (birth control) pill, work and make them less effective at preventing pregnancy. Talk to your doctor, who will discuss with you the most suitable type of contraception to use while you are taking Phenytoin Sodium.

Breast-feeding

Phenytoin Sodium passes into breast milk. You should not take Phenytoin Sodium if you are breast-feeding.

Driving and using machines

Phenytoin Sodium may cause dizziness or drowsiness, especially during the first few weeks of treatment. If you experience these symptoms, do not drive or use any tools or machinery.

Phenytoin Sodium contains lactose

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

Phenytoin Sodium contains sodium

Phenytoin Sodium 100 mg Capsules contain less than 1 mmol sodium (23 mg) per capsule, that is to say essentially 'sodium free'.

Phenytoin Sodium 300 mg Capsules contain 27 mg sodium (main component of cooking/table salt) in each capsule. This is equivalent to 1.3% of the recommended maximum daily dietary intake of sodium for an adult.

3. How to take Phenytoin Sodium

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

It is best to take Phenytoin Sodium at the same time each day.

Swallow the capsules whole, with plenty of water.

Adults

The amount of Phenytoin Sodium needed varies from one person to another. Most adults need between 200mg and 500mg a day either as a single or divided dose. Occasionally higher doses are needed.

Use in children and adolescents

Infants and children usually start on a dose that depends on their weight (5mg per day for every kg they weigh) and is given as a divided dose, twice a day. The dose is then adjusted up to a maximum of 300 mg a day.

Elderly and patients with kidney or liver disease

The dose of Phenytoin Sodium for elderly patients, patients with kidney or liver disease, or those who may be taking other medicines may also need careful consideration and adjustment by their doctor.

If you take more Phenytoin Sodium than you should

Phenytoin Sodium are dangerous in overdose. If you accidentally take too much Phenytoin Sodium contact your doctor at once or go to the nearest hospital casualty department. Always take the labelled medicine package with you, whether there are any Phenytoin Sodium left or not.

If you forget to take Phenytoin Sodium

If you forget to take a dose, take it as soon as you remember unless it is time for your next dose.

Do not take a double dose to make up for a forgotten dose.

If you stop taking Phenytoin Sodium

Do not stop taking Phenytoin Sodium unless your doctor tells you to. If you suddenly stop taking this medicine you may have a seizure. Should you need to stop taking Phenytoin Sodium, your doctor will have decided which is the best method for you.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Tell your doctor immediately if you experience any of the following symptoms after taking this medicine. Although they are very rare, these symptoms can be serious.

- Severe allergic reaction like swelling of eyelids, face, lips, mouth and/or throat, as well as the tongue which may cause difficulty breathing or swallowing (known as angioedema) and sudden wheeziness. **Stop taking your medicine immediately and tell your doctor.**
- If you develop a severe skin rash that causes blistering, (this can also affect the mouth and tongue). These may be signs of a condition known as Stevens Johnson Syndrome, or toxic epidermal necrolysis (TEN). **Your doctor will stop your treatment in these cases.**
- If you notice bruising, fever, you are looking pale or you have a severe sore throat. These may be the first signs of an abnormality of the blood, including decreases in the number of red cells, white cells or platelets. Your doctor may take regular blood samples to test for these effects.
- If you experience a serious skin reaction: a red, scaly rash with bumps under the skin and blisters. These may be signs of a condition known as acute generalized exanthematous pustulosis (AGEP). The frequency of this side effect is not known (cannot be estimated from available data).
- Skin rash and fever with swollen glands, particularly in the first two months of treatment, as these may be signs of a hypersensitivity reaction. If these are severe and you also experience pain and inflammation of the joints this could be related to a condition called systemic lupus erythematosus.
- If you experience confusion or have a severe mental illness, as this may be a sign that you have high amounts of phenytoin in your blood. On rare occasions, when the amount of phenytoin in the blood remains high, irreversible brain injury has occurred. Your doctor may test your blood to see how much phenytoin is in the blood and may change your dose.

Other side-effects that may occur are:

- **Effects on your nervous system:** Unusual eye movements, unsteadiness, difficulty in controlling movements, shaking, abnormal or uncoordinated movements, slurred speech, confusion, pins and needles or numbness, drowsiness, dizziness, vertigo, sleeplessness, nervousness, twitching muscles, headaches, and taste change.
- **Effects on your skin:** skin rash including measles-like reactions which are mild and hives (raised, itchy areas of skin).
- **Effects on your stomach and intestines:** feeling sick, being sick and constipation.
- **Effects on your blood and lymph system:** swelling of the lymph glands, a decrease in the number of a type of red blood cell (pure red cell aplasia).
- **Effects on your liver and kidney:** inflammation of the kidneys and liver, liver damage (seen as yellowing of the skin and whites of the eye).
- **Effects on your reproductive system:** changes in the shape of the penis, painful erection.
- **Effects on your hands, face and body:** changes in the hands with difficulty in straightening the fingers, changes in facial features, enlarged lips or gums, increased or abnormal body or facial hair.
- **Effects on medical tests:** increased levels of blood sugar, or decreased levels of blood calcium, folic acid and vitamin D and abnormal thyroid function test results. If you also do not get enough vitamin D in your diet or from exposure to sunlight, you may suffer from bone pain or fractures.
- **Effects on your respiratory system:** problems breathing, inflammation of the lining of the lung.
- **Effects on your immune system:** problems with the body's defence against infection, inflammation of the wall of the arteries.
- **Effects on your bones:** There have been reports of bone disorders including osteopenia and osteoporosis (thinning of the bone) and fractures. Check with your doctor or pharmacist if you are on long-term antiepileptic medication, have a history of osteoporosis, or take steroids.

Reporting of side effects
If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via Yellow Card Scheme Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Phenytoin Sodium

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton after EXP. The expiry date refers to the last day of that month.

Store below 30°C.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.

6. Contents of the pack and other information

What Phenytoin Sodium contains

- The active substance is phenytoin sodium. Each hard capsule contains 100 mg or 300 mg of phenytoin sodium.
- **The other ingredients are:**
  Phenytoin Sodium Milpharm 100 mg Capsule, Hard:
  Lactose monohydrate, magnesium stearate. The cap of the capsule contains erythrosine (E127), quinoline yellow (E104), gelatin and the body of capsule contains titanium dioxide (E171) and gelatin and printing ink (black) contains shellac (E904), black iron oxide (E172) and potassium hydroxide (E525).

Phenytoin Sodium Milpharm 300 mg Capsule, Hard:
Lactose monohydrate, magnesium stearate, silica, colloidal anhydrous. The cap of the capsule contains patent blue (E131), quinoline yellow (E104), gelatin and the body of capsule contains titanium dioxide (E171) and gelatin and printing ink (black) contains shellac (E904), black iron oxide (E172) and potassium hydroxide (E525).

What Phenytoin Sodium looks like and contents of the pack
Phenytoin Sodium Milpharm 100 mg Capsule, Hard is an orange cap/ white body, size 3 hard gelatin capsule, imprinted with 'PHN 100' on both cap and body with black ink, filled with white to off white powder.

Phenytoin Sodium Milpharm 300 mg Capsule, Hard is green trans cap/ white body, size 1 hard gelatin capsule, imprinted with 'PHN 300' on both cap and body with black ink, filled with white to off white powder.

Phenytoin Sodium Milpharm Capsules, Hard are marketed in Container pack (i.e. white opaque HDPE container closed with white opaque polypropylene closure). Each HDPE container contains silica gel as desiccant.

Pack size:
300 mg: 28 capsules.
100 mg: 84 capsules.

Marketing Authorisation Holder
Milpharm Limited
1 Roundwood Avenue,
Stockley Park,
Uxbridge,
UB11 1AF
United Kingdom

Manufacturer
APL Swift Services (Malta) Limited
HF26, Hal Far Industrial Estate, Hal Far,
Birzebbugia, BBG 3000, Malta

Or

Milpharm Limited
1 Roundwood Avenue,
Stockley Park,
Uxbridge,
UB11 1AF
United Kingdom

This leaflet was last revised in 10/2026.

Ref Ver: 1.0